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Non-Confidential Summary of Safety and Effectiveness

April 29, 2005

Axon Medical Inc.
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Salt Lake City, Utah 84119

Tel – (801) 484-3820
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Official Contact:	Joseph Orr – President
Proprietary or Trade Name:	AneFin 100
Common/Usual Name:	Rebreathing / Absorber
Primary Classification Name	Gas Scavenging Apparatus
Primary Classification Code:	CBN
Secondary Classification Name:	Rebreathing Device
Secondary Classification Code:	BYW
Primary Predicate Devices:	RFS Vacuum gauge scavenging circuit, Accutron - K033503 "Protect-OR" filter, Charcoal based scavenging device, Foregger - Pre-Amendment
Secondary Predicate:	Model A100 CO_2 absorber with bypass valve Penlon, 510(k) exempt Non invasive cardiac output monitor, NICO (Product code: CCK) Novametrix - K030886

Device Description: The AneFin combines an anesthetic gas absorber to remove anesthetic gas from inhaled air and a rebreathing hose which increases inspired CO_2 amounts which allows increased patient ventilation while preventing hypocapnia during emergence from volatile inhaled anesthesia.

Intended Use:
The AneFin 100 is intended to speed emergence from volatile inhaled anesthetics by removing unwanted anesthetic gases and increasing spontaneous breathing through partial rebreathing.

Environment of Use: Operating room, surgical suite, anywhere inhaled volatile anesthetics are administered.

Non-Confidential Summary of Safety and Effectiveness

Comparison to Predicate Devices to demonstrate substantial equivalence

Attribute	Proposed Device	RFS Vacuum scavenging K033503	Protect-OR scavenging device Pre-amendment	Model A100 CO_2 absorber bypass valve, exempt	Non-invasive cardiac output monitor, NICO K030886
Intended Use	Speed emergence from inhaled volatile anesthetics	Remove anesthetic agent from operating room	Remove anesthetic agent from operating room	Remove CO_2 and allow rapid build-up of CO_2 by rebreathing	Measure cardiac output by partial CO_2 rebreathing
Scavenging method	Charcoal adsorption	Vacuum system conveys waste gas out of operating room	Charcoal adsorption	Not applicable	Not applicable
Method of increasing CO_2	Dead space tubing placed between patient and Y-Piece.	Not applicable	Not applicable	Valve on absorber allows expired gas containing CO_2 to bypass absorber	Dead space tubing placed between patient and Y-Piece
Rebreathing Volume	431 ml max.	Not applicable	Not applicable	Depends on the volume of the breathing circuit	> 400 ml
Intended Population	Surgical Patients receiving inhaled anesthetics	Dental patients receiving inhaled anesthetics	Surgical Patients receiving inhaled anesthetics Same	Surgical Patients receiving inhaled anesthetics	Surgical Patients receiving inhaled anesthetics
Environment of Use	Operating Room	Operating Room, Dental Suite	Operating Room	Operating Room	Operating Room, ICU
Placement in circuit	Between endotracheal tube and Y-Piece	Gas evacuation port	Gas evacuation port	Between inspired and expired one-way valves	Between endotracheal tube and Y-piece
Materials	Activated charcoal, polypropylene housing and rebreathing hose	Not applicable	Activated Charcoal	Not applicable	Polypropylene housing and rebreathing hose

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the identified predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 2005

Axon Medical
Mr. Joseph Orr,
President
2355 South 1170 West, Suite D
Salt Lake City, Utah 84119

Re: K033028
Trade/Device Name: Anefin, Model 100
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-scavenging apparatus
Regulatory Class: II
Product Code: BYW
Dated: April 29, 2005
Received: May 2, 2005

Dear Mr. Orr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K033028 (To be assigned)

Device Name: AneFin 100

Indications for Use:

The AneFin 100 is intended to speed emergence from the effects of volatile inhaled anesthetics by removing unwanted anesthetic gases and increasing spontaneous breathing through partial rebreathing.

It is intended for use with only Isoflurane, Sevoflurane and Desflurane.

Prescription Use XX **or** **Over-the-counter use** _____
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033028